

70127-6

1/30/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Carrie Daniels, Agent for Novozymes Biologicals, Inc.
Exponent
1150 Connecticut Avenue, N.W.
Suite 1100
Washington DC 20036

RE: Revised Manufacturing Process and Label for Taegro Technical (EPA Reg. No. 70127-6)
OPP Decision Number: D480102

Dear Mr. Feinberg:

The Agency has reviewed your amended manufacturing process of Taegro Technical, supporting acute toxicity studies, confidential statement of formula (CSF) dated May 3, 2013, and the amended product label. A copy of the Agency's risk assessment dated January 13, 2014 is enclosed. BPPD has determined that these data for *Bacillus subtilis* Var. *amyloliquefaciens* FZB24 are acceptable to support the label amendment.

The label amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

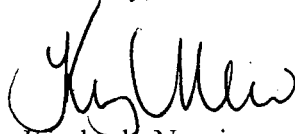
1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of the final printed labeling prior to releasing the product for shipment.

CONCURRENCES								
SYMBOL	▶ 7511P	7511P	7511P					
SURNAME	▶ [Signature]	Boyes	UNB					
DATE	▶ 1/30/14	1/30/14	1/30/14					

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA § 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any further questions regarding this, please do not hesitate to contact Susanne Gerrelli, at 703-308-8077 (cerrelli.susanne@epa.gov).

Sincerely,



Kimberly Nesci
Chief

Biopesticides and Pollution Prevention Division
Microbial Pesticides Branch (7511P)

Enclosures

For manufacturing purposes only

	% w/w
ACTIVE INGREDIENT: <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i> Strain FZB24*	79.9%
OTHER INGREDIENTS	20.1%
Total	100.0%

*Contains a minimum of 2.0×10^{11} Colony Forming Units (CFU)/gram.

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See additional precautionary statements on the [side/back] panel]
[this statement will be inserted if the label is printed on more than one sheet]

Net weight: _____ [Actual value to be inserted, generally 100 to 500 lbs.]

Novozymes Biologicals, Inc.
5400 Corporate Circle • Salem, VA 24153
1-888-744-5662

EPA Reg. No. 70127-6
EPA Est. No. 70127-VA-001
Made in the U.S.A.

ACCEPTED

JAN 30 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 70127-6

Batch code and Expiration Date: [Batch code and expiration date to be inserted]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION – Harmful if absorbed through skin, swallowed, or inhaled. Avoid breathing dust. Wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Avoid contact with skin, eyes, or clothing. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear waterproof gloves.

FIRST AID

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IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a Poison Control Center or doctor immediately for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.

ACCEPTED HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

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ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority had been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For formulation into fungicide products intended for use in/on crops and ornamental plants. This product may be used to formulate products for additional uses not listed on the manufacturing-use product (MP) label if the formulator, user group, or grower has complied with US EPA data submission requirements regarding the support of such uses.

WARRANTY: Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

TAEGR0 consists of living microbes. Store between 39°F (4°C) and 73 F (23°C), but do not exceed 95°F (35°C), and use within two years. Do not freeze. Close opened packages tightly.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container.

Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

The cardboard box should be offered for recycling, where available, or disposed of in a landfill.

[Note to reviewer: This product is sold in large plastic bags contained within cardboard boxes.]